STUDY INFORMED CONSENT

SNaP - Scaling up HPTN 074: a Cluster Randomized Implementation Trial of an Evidence-based Intervention for Antiretroviral Therapy for PWID in Vietnam

NCT number NCT03952520
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Consent to Participate in a Research Study
Adult Participants – Enrollment –People who inject drugs (PWID) - Subsample Cohort

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IRB Study # 18-2901
Consent Form Version Date: Version 2.3 dated 5 April 2021

Title of Study: SNaP - Scaling up HPTN 074: a Cluster Randomized Implementation Trial of an Evidence-based Intervention for Antiretroviral Therapy for PWID in Vietnam

Protocol Version 2.0, dated 26 September 2019; LOA 1

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You enrolled in the part of the study allowing us to access your ART and MAT information and you have been selected randomly to take part in a subsample cohort to allow us to re-contact you at a later date.
You will be asked to take part in an interview by phone at baseline, 12, 18 and 24 months where a brief questionnaire will be given. You will be asked to return 12 months, 18 months and 24 months later to the test site where a dried blood spot specimen will be collected for viral load testing. Up to 420 participants will be invited to participate in an additional costing questionnaire at baseline, and at 12 or 18 or 24 months depending on their enrollment date. If we are not able to contact you within 3 months from when you joined the study, you will not have the follow-up visits or phone interviews at 12, 18 and 24 months.
While you may likely benefit from the SNaP intervention, you may not directly benefit from taking part in the study. You may have problems if people learn that you are here for this study and think that you are infected with HIV or at risk of HIV because of sexual behavior or drug use. There may be a small risk of psychological distress by study questions. You can terminate the interview at any time.
If you are interested in learning more about this study, please continue reading below.

Introduction
You enrolled in the part of the study allowing us to access your ART and MAT information and you have been selected randomly to take part in a subsample cohort to allow us to re-contact you at a later date. Approximately 1500 PWID will be asked to take part in this subsample cohort.

How long will your part in this study last?
You will be in this study for 24 to 27 months.

What will happen if you take part in the study?

In this part of the study you will:

- Be asked to provide contact information to allow us to re-contact you at a later date and to obtain your locator information including a family member's.
- Be asked to take part in an interview by phone at baseline, 12, 18 and 24 months where a brief questionnaire will be given. The questionnaire will address your views of SNaP and factors that may affect your uptake of ART and MAT, including sociodemographic characteristics, injecting behaviors, social support, mental health and costs.
- Be asked to return 12 months, 18 months and 24 months later to the test site where a dried blood spot specimen will be collected for viral load testing.

Up to 420 participants will be invited to participate in an additional costing questionnaire at baseline and at 12-month or 18-month or 24-month visit, depending on their enrollment date.

We will call you every 3 to 4 months to ensure your contact information has not changed. If we are unable to reach you, we will contact a family member or friend, using the contact number that you had provide, to try to update your locator information.

You may be asked to take part in a qualitative in-depth interview 24 months after you enroll in this study to assess characteristics of high and low performing sites in depth. You will be asked to sign another informed consent to take part.

If we are not able to contact you within 3 months from when you joined the study, you will not have the follow-up visits or phone interviews at 12, 18 and 24 months.

We also want to keep your contacts so that we can contact you in the future if needed. You will be asked to give consent to be contacted for future studies.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge.
All PWID presenting at the 42 HIV test sites will be offered the SNaP intervention. While you may likely benefit from the SNaP intervention, you may not directly benefit from taking part in the study. Participants may benefit from being able to share their experiences and opinions about the SNaP intervention. Participants in the Tailored Approach (TA) implementation arm may benefit from potentially more effective implementation of SNaP.

What are the possible risks or discomforts involved with being in this study?

Social Impact Reporting

- We will make every effort to protect your privacy and confidentiality while you are in this study. However, it is possible that you could have problems if people learn that you are here for this study. People may think that you are infected with HIV or at risk of HIV because of sexual behavior or drug use. It is also possible that others may find out that you have been screened for this study and assume that you are a person who injects drugs. If people think you are infected with HIV or a person who injects drugs, this could cause you problems finding or keeping a job. Others may treat you unfairly, including your family and community.
- Further, it is possible that those you tell, will tell others that you are HIV-positive.

Blood collection

- Dried blood spots will be collected by a finger prick. You may have a slight pain when the finger is pricked. To reduce the possibility of pain, dried blood spot collection will be taken by trained staff. You may decline the dried blood spot collection with no consequence to your care.

In-Depth Interview

- There may be a small risk of psychological distress by study questions such as those concerning HIV risk, drug use, and disclosure of HIV serostatus. You may find answering questions about these issues upsetting: these questions will be asked in as sensitive a manner as possible, and you may decline to answer at any time. If you experience emotional upset during the interview, the research staff will be trained on how to handle these situations and the principal investigators will be available to speak with you if needed.

Specific and appropriate protocols will be in place to ensure a participant's safety should a research staff member feel that a participant is in danger of harming himself or others during the course of a study visit. We will also remind participants that they can terminate the interview at any time.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

You will receive an identification number (PID) and this number will be used for all interviews and collection of lab specimens. This PID will not be linked to your name, and no other information that would disclose the participant's identity will be found on any interview or specimen label or barcode label. Data will be kept without serostatus or injecting drug use identification in locked cabinets at the University of North Carolina (UNC) Project Vietnam office in Hanoi or designated offices at sites. Only the consent form, tracker form and tracker computer will link the participant's name to the identification number. If appropriate, we will maintain contact with participants using a computerized tracking system. In addition,

interviewing and office staff will sign a "confidentiality pledge" prior to having contact with participants.

All study procedures will be administered by trained study staff in a private room. Study interviews will be administered by trained study staff through telephone. If names and identifying information are collected, a logbook will be used to your identifying information with your study identification number (PID); personal identifiers will not be stored in the data set. The logbook will be kept in a locked cabinet, separate from all other study file cabinets, in a locked project office room; an electronic copy will be saved on a password-protected, encrypted computer. All data, notes, and audio- recordings will also be kept on a password-protected, encrypted computer. Access to the locked files and security passwords will be given only to the PIs, UNC-Vietnam In-Country Director, Research Manager and select well-trained project staff.

The logbook will be destroyed, and the electronic copy deleted 9 months after the end of data collection. Tapes of qualitative interviews will be destroyed within one year of being transcribed electronically. Raw data files will be destroyed one year after electronic coding. Blood samples will be incinerated after no more than 10 years of storage in lab facilities.

Although study sites will make every effort to protect participant privacy and confidentiality, it is possible that participants' involvement in the study could become known to others, and that social harms may result (i.e., because participants could become known as HIV-infected). For example, participants could be treated unfairly or discriminated against, or could have problems being accepted by their families and/or communities.

The study team will try to protect the privacy of your study records and test results, to the extent permitted by law, but cannot guarantee that your study records and test results will never be released to others. Unless required by law or unless you give written permission, study records that identify you will not be released to other parties or entities. However, your study records may be reviewed by various government agencies that have a legal right to do so, such as the sponsor of the study (US National Institutes of Health (NIH), the University of North Carolina at Chapel Hill Institutional Review Boards and the Institutional Review Board for Ethics in Biomedical Research – Hanoi Medical University, the Vietnam Administration for HIV/AIDS Control (VAAC), study staff and study monitors. It is also possible that a court or other government agency could order that study records identifying you be released to others. Any publication or presentation of the results of findings of this study will not use your name and will not include any information that will identify you.

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required

by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What will happen if you are injured by this research?
If you have any health problems between visits, please contact the study staff. If you have a medical emergency that requires immediate care, please call 115. If you are injured as a result of being in this study, the District Health Center will give you immediate necessary treatment for your injuries. You *will* have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program for monetary compensation or other forms of compensation for such injuries either through this institution or the NIH. You do not give up any legal rights by signing this consent form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty.

Reasons Why You May Be Withdrawn From The Study Without Your Consent:
You may be removed from the study without your consent for the following reasons:

- The study is stopped or cancelled.
- Staying in the study would be harmful to you.
- You are not able to attend study visits or complete the study procedures.

If you choose not to be in the study, what other treatment options do you have?
If you choose not to take part in this study, it will have no effect on your access to regular services at this site.

Will you receive anything for being in this study?
You will receive VND 100,000 at the end of each study visit to compensate for your time and travel.

Will it cost you anything to be in this study?
There will be no cost to you for study-related visits or other procedures.

Who is sponsoring this study?
This research is funded by the US National Institute on Drug Abuse (NIDA), US National Institutes of Health (NIH). This means that the research team is being paid by the sponsor. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Contact Information
You will be asked to provide your address and phone number(s). The staff will ask you for names of people who will always know how to find you and places where you can be found. It is possible that the staff may visit you at your house or contact one of the people on your contact list if you are not able to attend your visits or if the staff have important information for you. If we talk to people on this list, we will not tell them why we are trying to reach you. If you are not willing to give us this information, you should not agree to be in this study. We will also ask you to give us contact information at the last study visit so we can contact you and share with you the results of this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
If you have questions or concerns as a research participant, please contact:

- Dr. Le Minh Giang, Head of Department of Epidemiology, Institute for Preventive and Public Health, Hanoi Medical University at +84 2435741596 or at leminhgiang@hmu.edu.vn
- Hanoi Medical University Institutional Ethical Review Board in Biomedical Research at +84 2438527622 or by email to irb@hmu.edu.vn

Or you may contact the University of North Carolina at Chapel Hill Institutional Review Board (IRB) at +1-919-966-3113 or by email to IRB_subjects@unc.edu.

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Local Principal Investigator: Dr. Le Minh Giang
US Principal Investigator: Dr. Vivian Go
US Principal Investigator: Dr. William Miller

SIGNATURES: Enrollment Consent For People who inject drugs (PWID) - Subsample Cohort

Participant's Agreement:
Please indicate by writing your initials or making your mark below if you agree or not to be contacted by the study team for future studies, when appropriate

I agree _____

I do not agree _____

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to enroll into this study, please check this box:

☐

And please sign your name, make your mark, or place your thumbprint below.

PART A: LITERATE PARTICIPANT

Participant is literate ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

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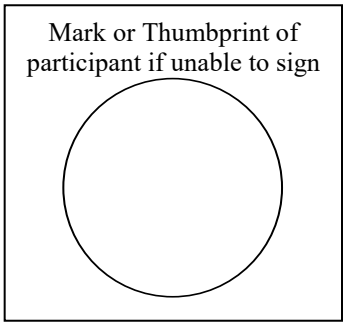
PART B : ILLITERATE PARTICIPANT

Participant is illiterate ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The study staff must write participant's name and date of consent below.



Participant Mark or Thumbprint

_____		_____
Participant Name (print)		Date

Participant name and date written by _____ on _____

_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

_____	_____	_____
Witness Name (print)	Witness Signature	Date